

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 510 and 520

DDM

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Certifier A. Corbin

New Animal Drugs; Change of Sponsor

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the animal drug regulations to reflect a change of sponsor for two approved new animal drug applications (NADAs) from Zema Corp. to Virbac AH, Inc.

DATES: This rule is effective [*insert date of publication in the Federal Register*].

FOR FURTHER INFORMATION CONTACT: David R. Newkirk, Center for Veterinary Medicine (HFV-100), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301-827-6967, e-mail: david.newkirk@fda.gov.

SUPPLEMENTARY INFORMATION: Zema Corp., P.O. Box 12803, Research Triangle Park, Durham, NC 27709, has informed FDA that it has transferred ownership of, and all rights and interest in, the following two approved NADAs to Virbac AH, Inc., 3200 Meacham Blvd., Ft. Worth, TX 76137:

Application No.	21 CFR Section	Trade Name
NADA 102-942	520.580	PULVEX Multipurpose Worm Caps
NADA 091-260	520.1804	PULVEX Worm Caps

Accordingly, the agency is amending the regulations in 21 CFR 520.580 and 520.1804 to reflect the transfer of ownership.

Following these changes of sponsorship, Zema Corp. is no longer the sponsor of an approved application. Accordingly, the agency is amending the regulations in 21 CFR 510.600(c) to remove the entries for Zema Corp.

This rule does not meet the definition of “rule” in 5 U.S.C. 804(3)(A) because it is a rule of “particular applicability.” Therefore, it is not subject to the congressional review requirements in 5 U.S.C. 801–808.

List of Subjects

21 CFR Part 510

Administrative practice and procedure, Animal drugs, Labeling, Reporting and recordkeeping requirements.

21 CFR Part 520

Animal drugs.

■ Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs and redelegated to the Center for Veterinary Medicine, 21 CFR parts 510 and 520 are amended as follows:

PART 510—NEW ANIMAL DRUGS

■ 1. The authority citation for 21 CFR part 510 continues to read as follows:

Authority: 21 U.S.C. 321, 331, 351, 352, 353, 360b, 371, 379e.

§ 510.600 [Amended]

■ 2. Section 510.600 is amended in the table in paragraph (c)(1) by removing the entry for “Zema Corp.” and in the table in paragraph (c)(2) by removing the entry for “050906”.

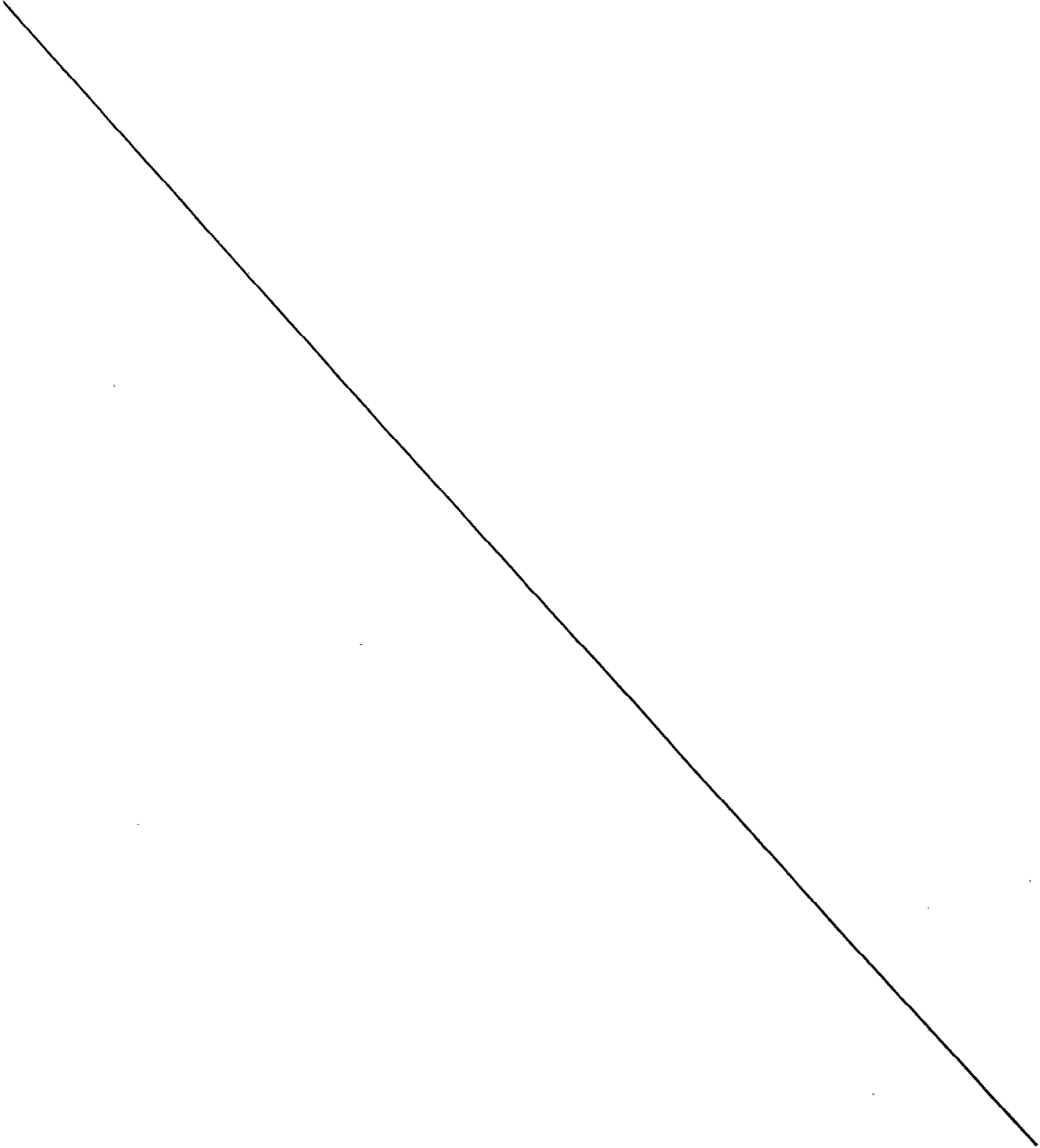
PART 520—ORAL DOSAGE FORM NEW ANIMAL DRUGS

■ 3. The authority citation for 21 CFR part 520 continues to read as follows:

Authority: 21 U.S.C. 360b.

§ 520.580 [Amended]

- 4. Section 520.580 is amended in paragraph (b)(1) by removing “050906” and by adding in its place “051311”.



§ 520.1804 [Amended]

■ 5. Section 520.1804 is amended in paragraph (b) by removing "050906" and by adding in its place "051311".

Dated: May 18, 2004
May 18, 2004.

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[FR Doc. 04-????? Filed ??-??-04; 8:45 am]

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